

## MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

### **CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR OPEN HEART SURGERY SERVICES**

(By the authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

#### **Section 1. Applicability**

Sec. 1. (1) These standards are requirements for approval and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve open heart surgery services.

(2) Open heart surgery is a covered clinical service for purposes of Part 222 of the Code.

(3) The Department shall use sections 3, 4, 5, 6, 8, and 9, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section 7 in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

#### **Section 2. Definitions**

Sec. 2. (1) As used in these standards:

(a) "Adult open heart surgery" means open heart surgery offered and provided to individuals age 15 and older.

(b) "Cardiac surgical team" means the designated specialists and support personnel who consistently work together in the performance of open heart surgery.

(c) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(d) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(e) "Department" means the Michigan Department Of Community Health (MDCH).

(f) "ICD-9-CM code" means the disease codes and nomenclature found in the International Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital Activities for the U.S. National Center for Health Statistics.

(g) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-8 to 1396v.

(h) "Michigan inpatient data base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(i) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These procedures may be performed off-pump (beating heart), although a heart-lung pump is still available during the procedure.

(j) "Open heart surgery service" means a hospital program that is staffed with surgical teams and other support staff for the performance of open heart surgical procedures. An open heart surgery service performs open heart surgery procedures on an emergent, urgent and scheduled basis.

(k) "Pediatric open heart surgery" means open heart surgery offered and provided to infants and children age 14 and below, and to other individuals with congenital heart disease as defined by the ICD-9-CM codes of 745.0 through 747.99.

(l) "Planning area" means the groups of counties shown in Section 10.

(2) The definitions in Part 222 shall apply to these standards.

### **Section 3. Requirements for approval -- all applicants**

Sec. 3. (1) An applicant proposing to initiate either adult or pediatric open heart surgery as a new service shall have in place, or meet the CON review standards for initiation of diagnostic and therapeutic adult or pediatric cardiac catheterization services, respectively.

(2) A hospital proposing to initiate open heart surgery as a new service shall have a written consulting agreement with a hospital which has an existing active open heart surgery service performing a minimum of 350 open heart surgical procedures per year. The agreement must specify that the existing service shall, for the first 3 years of operation of the new service, provide the following services to the applicant hospital:

(a) Receive and make recommendations on the proposed design of surgical and support areas that may be required;

(b) Provide staff training recommendations for all personnel associated with the new proposed service;

(c) Provide recommendations on staffing needs for the proposed service; and

(d) Work with the medical staff and governing body to design and implement a process that will at least annually measure, evaluate, and report to the medical staff and governing body, the clinical outcomes of the new service, including: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and (iv) Infection rates.

(3) An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

### **Section 4. Requirements for approval -- all applicants for adult open heart surgery services**

Sec. 4. An applicant proposing to initiate adult (non-pediatric) open heart surgery as a new service shall demonstrate that 300 adult open heart surgical procedures result from application of the methodology described in Section 8.

### **Section 5. Requirements for approval -- all applicants for pediatric open heart surgery services**

Sec. 5. An applicant proposing to initiate pediatric open heart surgery as a new service shall demonstrate that 100 pediatric open heart surgical procedures result from application of the methodology described in Section 9.

### **Section 6. Requirements for MIDB data commitments**

Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric open heart surgery services, an applicant shall demonstrate or agree, as applicable, to all of the following.

(1) A hospital(s) whose adult MIDB data is used in support of a CON application for adult open heart surgery services shall not use any of its adult MIDB data in support of any other application for adult open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support.

(2) A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric open heart surgery services shall not use any of its pediatric MIDB data in support of any other application for pediatric open heart surgery services prior to 7 years after the initiation of the open heart surgery service for which MIDB data were used to support.

(3) The hospital(s) committing MIDB data does not currently operate an adult or pediatric open heart surgery service or have a valid CON issued under former Part 221 or Part 222 to operate an adult or pediatric open heart surgery service.

(4) The hospital(s) committing MIDB data is located in the same planning area as the hospital to which MIDB data is being proposed to be committed.

(5) The hospital(s) committing MIDB data to a CON application has completed the departmental form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

(6) The hospital(s) committing MIDB data to an application is regularly admitting patients as of the date the Director makes the final decision on that application, under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

#### **Section 7. Project delivery requirements -- terms of approval for all applicants**

Sec. 7. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the following terms of CON approval:

- (a) Compliance with these standards.
  - (b) Compliance with applicable operating standards.
  - (c) Compliance with the following quality assurance standards:
    - (i) The open heart surgery service shall be operating at an annual level of 300 adult open heart surgical procedures or 100 pediatric open heart surgical procedures, as applicable, by the end of the third 12 full months of operation.
    - (ii) Each physician credentialed by the applicant hospital to perform adult open heart surgery procedures, as the attending surgeon, shall perform a minimum of 50 adult open heart surgery procedures per year. The annual case load for a physician means adult open heart surgery procedures performed by that physician, as the attending surgeon, in any hospital or combination of hospitals.
    - (iii) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24 hour on-call availability.
    - (iv) The service shall have the capability for rapid mobilization of a cardiac surgical team for emergency procedures 24 hours a day, 7 days a week.
    - (v) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.
  - (d) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
    - (i) provide open heart surgery services to all individuals based on the clinical indications of need for the service and not on ability to pay or source of payment; and
    - (ii) maintain information by source of payment to indicate the volume of care from each source provided annually.
- Compliance with selective contracting requirements shall not be construed as a violation of this term.
- (e) The applicant shall prepare and present to the medical staff and governing body reports describing activities in the open heart surgery service including complication rates and other morbidity and mortality data.
  - (f) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include but is not limited to annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the

required data in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(g) The applicant shall provide the Department with a notice stating the date on which the first approved service is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the governing body of the applicant.

## **Section 8. Methodology for computing the number of adult open heart surgical procedures**

Sec. 8. (1) An applicant shall apply the methodology set forth in this section for computing the number of adult open heart surgical procedures. In applying discharge data in the methodology, each applicable inpatient record shall be used only once. This methodology shall utilize only the inpatient discharges that have one or more of the cardiac diagnoses in Subsection (2). In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent Michigan Inpatient Data Base available to the Department, an applicant shall identify the discharges that were from patients aged 15 years and older. These discharges shall be considered "adult discharges."

(b) Using the "adult discharges" identified in Subdivision (a), an applicant shall count the number of discharges with a principal diagnosis corresponding to each of the first six categories (Groups A through F) of ICD-9-CM codes listed in Subsection (2). When a patient has a principal diagnosis which falls into one of these six groups (exclude Other Heart Conditions), then they shall be categorized by that diagnosis and their case shall be removed from the data to be used in Subdivisions (c), (d) and (e) so that each applicable inpatient record shall be counted only once.

(c) The procedure in this subdivision shall be used to determine in which diagnosis group each appropriate inpatient record is to be included. The first four non-principal diagnosis codes shall be used to determine the categorization of the remaining records. The sequence of the ICD-9-CM groupings in Subsection (2) shall be followed exactly. For each individual inpatient record, an applicant shall start with the first category of Valves (Group A: ICD-9-CM codes 394.0-397.99 and 424.0-424.99) and shall search through the first four non-principal diagnosis codes to determine if any fall into this grouping. If a record has a non-principal diagnosis code for this grouping, it shall be assigned to the Valve group and shall be removed from all subsequent search actions. The remaining inpatient records shall then be searched for the presence of the Valve codes. After all the inpatient records with Valve codes have been removed, the above procedure shall be repeated for each of the remaining five groups (Groups B through F) in sequence. For example: the next step would be a search of remaining inpatient records for codes representing the Congenital Anomalies (Group B: ICD-9-CM codes 745.0-747.99). NOTE: The above procedure shall not apply to the All Other Heart Conditions category (Group G).

(d) Add the count of the number of records for each principal diagnosis group (separately) that was identified under Subdivision (b) with the count of the number of records for its respective non-principal diagnosis group identified under Subdivision (c). The end result shall be a total count for each of the first six diagnostic groups (excluding All Other Heart Conditions - Group G).

(e) Using the remaining discharge data, an applicant shall count the discharges that were from patients that have a principal diagnosis or any of the first four non-principal diagnoses using the ICD-9-CM codes for the All Other Heart Conditions category (Group G) listed in Subsection (2).

(f) An applicant shall multiply the count for each ICD-9-CM category listed in Subsection (2) by its corresponding Adult Open Heart Utilization Weight and add the products together to produce the number of adult open heart surgical procedures for the applicant.

(2) For purposes of the adult open heart methodology, the following cardiac diagnoses shall be used:

## DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL PROCEDURES

<u>Group</u>	<u>Major ICD-9-CM Code Group</u>	<u>Category</u>	<u>Adult Open Heart Utilization Weights</u>
A	394 - 397.9 424 - 424.99	Valves	.0808
B	745 - 747.99	Congenital Anomalies	.0766
C	414 - 414.99	Other Chronic Ischemic	.0632
D	411 - 411.99	Other Acute & Sub Acute Ischemic	.0510
E	410 - 410.99	Acute Myocardial Infarct	.0400
F	413 - 413.99 786.5 - 786.59	Angina & Chest Pain	.0102
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G	390 - 393 398 - 405.99 412, 415 - 423.9 425 - 429.99	All Other Heart Conditions	.0029

(3) The major ICD-9-CM groupings and Open Heart utilization weights in Subsection (2) are based on the work of the former Division of Planning and Policy Development, Michigan Department of Public Health utilizing the 1986 Michigan Inpatient Data Base.

(4) Each applicant shall provide access to verifiable hospital-specific data and documentation using a format established by the Department and a mutually agreed upon media.

### **Section 9. Methodology for computing the number of pediatric open heart surgical procedures**

Sec. 9. (1) An applicant shall apply the methodology set forth in this section for computing the number of pediatric open heart surgical procedures. In applying discharge data in the methodology, each applicable inpatient record is used only once. This methodology shall utilize only those inpatient discharges that have one or more of the cardiac diagnoses listed in Subsection (2). In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent Michigan Inpatient Data Base available to the Department, an applicant shall count the discharges that were from patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "Congenital Anomalies" category in Subsection (2). Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from the discharge data.

(b) Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that were from patients aged 14 years and younger. These discharges shall be known as the "pediatric discharges."

(c) Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "Other Heart" category in Subsection (2). Discharge records which do not have one or more of the Other Heart codes listed in Subsection (2) shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(d) An applicant shall multiply the count for the "Congenital" and "Other Heart" categories by the corresponding Pediatric Open Heart Utilization Weight and add the products together to produce the number of pediatric open heart surgical procedures for the applicant.

(2) For purposes of the pediatric open heart methodology, the following diagnoses shall be used:

#### DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL PROCEDURES

<u>Major ICD-9-CM Grouping</u>	<u>Category</u>	<u>Pediatric Open Heart Utilization Weights</u>
745.0-747.99	Congenital Anomalies	.1286
390-429.99 786.5-786.59	Other Heart	.0147

(3) The major ICD-9-CM groupings and Pediatric Open Heart Utilization Weights are based on the work of the former Division of Planning and Policy Development, Michigan Department of Public Health, utilizing the 1986 Michigan Inpatient Data Base.

(4) Each applicant must provide access to verifiable hospital-specific data and documentation using a format established by the Department and in a mutually agreed upon media.

### Section 10. Planning Areas

Sec. 10. Counties assigned to each planning area are as follows:

<u>PLANNING AREA</u>	<u>COUNTIES</u>		
1	LIVINGSTON MACOMB WAYNE	MONROE OAKLAND	ST. CLAIR WASHTENAW
2	CLINTON EATON	HILLSDALE INGHAM	JACKSON LENAWEE
3	BARRY BERRIEN BRANCH	CALHOUN CASS KALAMAZOO	ST. JOSEPH VAN BUREN
4	ALLEGAN IONIA KENT LAKE	MASON MECOSTA MONTCALM MUSKEGON	NEWAYGO OCEANA OSCEOLA OTTAWA
5	GENESEE	LAPEER	SHIAWASSEE
6	ARENAC BAY CLARE GLADWIN GRATIOT	HURON IOSCO ISABELLA MIDLAND OGEMAW	ROSCOMMON SAGINAW SANILAC TUSCOLA

7	ALCONA	CRAWFORD	MISSAUKEE
	ALPENA	EMMET	MONTMORENCY
	ANTRIM	GD TRAVERSE	OSCODA
	BENZIE	KALKASKA	OTSEGO
	CHARLEVOIX	LEELANAU	PRESQUE ISLE
	CHEBOYGAN	MANISTEE	WEXFORD
8	ALGER	GOGEBIC	MACKINAC
	BARAGA	HOUGHTON	MARQUETTE
	CHIPPEWA	IRON	MENOMINEE
	DELTA	KEWEENAW	ONTONAGON
	DICKINSON	LUCE	SCHOOLCRAFT

#### **Section 11. Application of Rule 325.9403**

Sec. 11. (1) Pursuant to CON rule 325.9403, a CON for open heart surgery services approved under these standards or standards that became effective on December 5, 1988 shall expire 1 year from its effective date, unless the project is initiated. One 6-month extension may be granted by the Department if the applicant shows that substantial progress toward initiation of the approved open heart surgery service has been made and an obligation for capital expenditure, if any, will occur within the extended time period.

(2) For purposes of open heart surgery services, "initiated" means when the first open heart surgery procedure is performed.

#### **Section 12. Effect on prior planning policies; comparative reviews**

Sec. 12. (1) These CON Review Standards supersede and replace the CON Review Standards for Open Heart Surgery Services approved by the CON Commission on March 11, 2003 and effective on May 12, 2003.

(2) Hospitals recognized by the Department pursuant to the prior State Medical Facilities Plan (SMFP) 1985-90 Planning Policies Pertaining to Cardiac Services as "Level II" cardiac service providers shall not be considered open heart surgery services providers as defined in Section 2. Those hospitals recognized by the Department as Level II providers under Part 221 may continue to provide Level II cardiac services consistent with the 1985-90 State Medical Facilities Plan.

(3) Projects reviewed under these standards shall not be subject to comparative review.